

Remarks

Favorable consideration of this application is respectfully requested in view of the foregoing amendment and the following remarks.

Claims 1-4, 6 and 8-12 are pending. Claims 1-4, 6 and 8-12 have been rejected. Claims 1 and 12 have been amended. No new matter has been added.

**I. The Rejection of Claims 1-4, 6, 8-9, 11 and 12 Under 35 U.S.C. §112, Second Paragraph, May Properly Be Withdrawn.**

Claims 1-4, 6, 8-9, 11 and 12 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite. With respect to claim 1, the Examiner asserts that there is no material difference in scope seen for reciting R6 forms ring with R7 and then on the next line stating R7 forms ring with R6. With respect to claim 12, the Examiner asserts that this claim is indeterminate scope in view of the phrase "activating a cannabinoid CB1 receptor."

In response, claim 1 has been amended to delete the phrase "R7 forms together with R6 a 4-7 membered saturated heterocyclic ring, optionally containing a further heteroatom selected from O and S", and claim 12 has been amended to recite specific disorders that may be associated with activation of the cannabinoid CB1 receptor. Support for the disorders recited in claim 12 is found in the specification, e.g., page 10, lines 20-23.

In view of the above, withdrawal of the rejection of claims 1-4, 6, 8-9, 11 and 12 under 35 U.S.C. §112, second paragraph, is respectfully requested.

**II. The Rejection of Claims 1-4, 6, And 8-12 Under 35 U.S.C. §112, First Paragraph, May Properly Be Withdrawn.**

Claims 1-4, 6, and 8-12 has been rejected under 35 U.S.C. §112, first paragraph. The Examiner asserts that the specification, while being enabling for unfused piperazines, does not reasonably provide enablement for fused piperazines. In particular, the Examiner asserts that the starting material sources for ortho-fused piperazines resulting from the joining of R6/R7 groups are not seen but are required. The Examiner also asserts that the specification is silent as to the availability of necessary reactants needed to prepare such ring systems or if they are commercially available. The Examiner further asserts that as there are no such fused compounds that have been made corresponding to the instant scope there is no reasonable basis for assuming that the myriad of compounds embraced by all the generic claims will all

share the same physiological properties since they are so structurally dissimilar as to be chemically non-equivalent and there is no basis in the prior art for assuming the same.

Applicant respectfully traverses this rejection and submits that the specification is enabling for claims 1-4, 6, and 8-12 for the reasons stated below.

It is asserted that compounds containing a fused piperazine ring are specifically described in Examples 2 and 3 of the specification. Example 2 also includes a detailed synthesis of the intermediate amine according to formula III (page 5) wherein "R6 form together with R7 a 6-membered saturated heterocyclic ring, i.e., (S)-octahydro-2H-pyrido[1,2-a]pyrazine (see page 15, line 6). In addition, activity information for the compound of example 2 is presented in Table 1 (page 26, second entry) showing the "fused piperazine" compound to have a high potency on the CB1 receptor, while compound 2 was also found active *in vivo* as measured in the Tail Flick Latency Test in the mouse (see page 28, lines 13-14). Accordingly, since the specification provides 1) examples of compounds containing a fused piperazine ring, 2) how to synthesize compounds containing a fused piperazine ring and 3) that compounds containing the fused piperazine ring have high potency on the CB1 receptor and are active *in vivo* in an animal model of pain, the specification enables claims 1-4, 6, and 8-12.

In view of the above, withdrawal of the rejection of claims 1-4, 6, 8-12 under 35 U.S.C. §112, first paragraph, is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, she is requested to call the undersigned at the number listed below.

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